

**REMARKS/ARGUMENTS****A. Status of the Claims**

Claims 33-57 were pending, with claims 48-50 and 52-55 having been withdrawn, at the time the Action was mailed. Claims 33, 36-41, 46-47 and 51 have now been amended, as shown above and discussed in greater detail below. Claim 35 was canceled. Claims 63 and 64 are new. No new matter was added in any of these amendments or by the addition of this new claim. Therefore, claims 33, 34, 36-57, 63 and 64 are currently pending, of which claims 48-50 and 52-55 are withdrawn.

**B. Amendments to the Specification**

In view of the new matter objections discussed below, Applicants have further amended two paragraphs of the Specification. The changes relative to the paragraphs as originally filed are that the two sentences providing the incorrect weight ranges have now been deleted. Specifically the following two sentences, both from the original Specification at page 7, have been deleted:

The water-insoluble swellable mucoadhesive polymer may be present in the pH-sensitive mucoadhesive layer at a concentration of from 0.1% to 20% by weight.

(from second full paragraph on page 7)

Preferably, it is present at a concentration of from 0.05% to 10% by weight.

(from third full paragraph on page 7)

The original ranges corresponded to the gel aspect of the invention, not the bi-layer wax-film composite aspect. Since both sentences are discussed in the context of the bi-layer wax-film, the error is obvious, especially in light of Example 8. *See* MPEP § 2163.07(a)(I). Support for deleting the incorrect ranges is provided in Table 1 (page 30), which provides ample evidence

that Applicants contemplated both (1) higher weight percentages for the water-insoluble swellable mucoadhesive polymer within the pH-sensitive mucoadhesive layer and (2) higher weight percentages for the pH-sensitive polymer within the pH-sensitive mucoadhesive layer. None of these amendments result in the addition of new matter.

### C. Amendments to the Claims

Claim 33 was amended as shown above. Support for the adjectives “anionic” is provided, for example, by the following statement:

No references or other prior art could be found that describe the use of mucoadhesive gels comprised of **anionic** polymers, that when applied to the skin or mucosal surfaces, form films due to effect of pH on the solubility of the **anionic** polymers.

The Specification at page 17 (emphasis added). This passage also implies a preference for anionic polymers, thereby providing support for the proviso “free of any neutral polymers.” Anionic, cationic and neutral polymers are further discussed, for example, at the bottom of page 16 and top of page 17 of the original disclosure.

Support for the proviso “free of any natural polymers” is based at least on the following: The term “natural polymers” is found in the title of a reference cited on page 41 of the original disclosure. This positive recitation of this term provides a basis for its exclusion from the currently pending claim. *See* MPEP § 2173.05(i). Also Applicants make consistent use of the adjective “natural” and its opposite “synthetic,” for example, when discussing a “synthetic or naturally occurring substance” or when discussing “synthetic or natural small molecules.” *See* Specification at page 12. Furthermore, Applicants characterize the various Eudragit polymers that feature in many of the examples of the original disclosure as being “synthetic.” *See* Specification at page 16. Taken together, the original disclosure, therefore, provides sufficient support for the proviso “free of any natural polymers.”

Claims 36-40, 46-47 and 51 were amended to change the claim dependency from 35 to 33. Several of these claims were also amended to reflect the updated antecedent basis of two claim terms.

Claim 47 was amended to remove exemplary language. The list of different types of active pharmaceuticals was moved from claim 47 to new claim 64. Minor typographical errors were corrected as well.

Claim 41 was amended to change the claim dependency from 35 to 38 and to specify Eudragit S100. Support for Eudragit S100 is provided, for example by Figure 2 and Examples 8, 9 and 11 (pages 30-32) of the original disclosure.

Support for the Noveon/Eudragit S100 ratio range from 2:1 to 4:1 in new claim 63 is provided by Examples 8 & 9 and Figure 2 of the original disclosure. Figure 2 shows significant adhesion times when the Noveon/Eudragit S100 weight ratio is 2:1, 3:1 and 4:1. Example 8 further comments upon this observation, stating that “the weight ratio of each Noveon and Eudragit S100 polymers used in the pH-sensitive mucoadhesive layer significantly affected the adhesive time on the glass.” The Specification at page 31. Finally, the importance of adhesive times is provided throughout the application, for example in the abstract, which states:

The wax-film composites comprise a bi-layer film having both the said pH-sensitive mucoadhesive layer to **promote strong adherence** to the skin and mucosal surfaces as well as a specially bonded wax layer intended to extend the **adherence of the film to tissues for a prolonged period of time.**”

Abstract of Specification (emphasis added).

None of these amendments result in the addition of new matter.

**D. The New Matter Objection Is Overcome**

The Action rejected the amendments to the Specification submitted in Applicants' response filed March 23, 2009 ("the Previous Response") under 35 U.S.C. § 132(a) for allegedly introducing new matter. Applicants disagree, but in the interest of securing swift allowance, Applicants have canceled parts of these amendments as discussed in detail above. "An amendment to correct obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also the appropriate correction." MPEP § 2163.07(a)(I). One appropriate correction would have been to introduce the correct ranges; however, since that was objected to, Applicants have now chosen another appropriate correction, namely simply deleting the incorrect ranges. Based on this, Applicants submit that this objection is overcome and respectfully request that it be withdrawn.

**E. The Written Description Rejections Are Overcome**

The Action rejected claim 38 and 40 under 35 U.S.C. § 112, first paragraph, for allegedly not providing sufficient support for the weight percentage ranges of Noveon and Eudragit, respectively. Applicants disagree, but in the interest of securing swift allowance, Applicants have amended both of these claims, deleting these ranges, as shown above. Applicants have also introduced new claim 63, which adds a limitation corresponding to a Noveon/Eudragit S100 weight ratio from 2:1 to 4:1. Support for this range as provided in the original disclosure as discussed in detail above. Applicants therefore respectfully request that these rejections be withdrawn.

**F. The Obviousness Rejection Is Overcome**

The Action rejects claims 33-47, 51 and 56-57 as obvious over U.S. Patent 6,562,363 to Mantelle *et al.* ("Mantelle") in view of U.S. Patent 4,715,369 to Suzuki *et al.* ("Suzuki").

Applicants respectfully request the Examiner to reconsider and withdraw this rejection in view of the amendments above and the comments below.

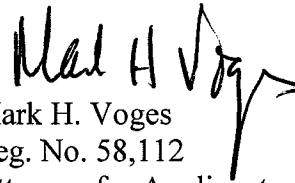
Claim 33 has been amended to include the proviso “free of any natural polymers and free of any neutral polymers”. Support in the original disclosure therefor is indicated above. None of the 85 compositions disclosed by Mantelle’s patent are free of both natural polymers and free of neutral polymers. For example, most of Mantelle’s compositions comprise polyvinyl pyrrolidone (PVP) and/or ethyl cellulose, both of which are neutral polymers. Those examples of Mantelle that **do not** contain either PVP or ethyl cellulose, **do** contain a natural polymer, either karaya gum (Examples 7, 13-14, 17 and 21-27), alginic acid (Examples 13 and 17) or soy polysaccharide (Example 14). In contrast, all the presently pending claims now require that the pH-sensitive mucoadhesive layer comprise at least two anionic polymers and exclude both neutral polymers and natural polymers from. Mantelle alone therefore fails to teach or suggest all the limitations of the claimed invention. Since Suzuki “is used primarily for the disclosure of a wax backing layer” (the Action at page 4), the combination of Mantelle and Suzuki also fails to teach or suggest all the limitations of the claimed invention.

For at least the above reasons, Applicants submit that the obviousness rejection of claim 33 and all the claims that depend therefrom is both overcome and moot. Applicants therefore respectfully request that this rejection be withdrawn.

**G. Conclusion**

Applicants believe that the present document is a full and complete response to the Action. The present case is in condition for allowance and such favorable action is requested. The Examiner is invited to contact the undersigned Attorney at (512) 536-3116 with any questions, comments, or suggestions relating to the referenced patent application.

Respectfully submitted,



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